REMARKS

Reconsideration of the above-identified application is respectfully requested.

Applicants wish to thank the Examiner for the telephonic interview dated February 8, 2007.

Claims 1–7, 9–14, 16, and 19 remain pending in the application. New claims 20–27 have been added with the above amendment. Support for new claim 20 is found on page 18, line 5 of the specification or in paragraph [0047] of the published application. Claims 8 and 15 have been cancelled. Claim 21 furthers define the composite sheet. Support for claim 21 is found in paragraph [0040] of the published application. Claims 22–27 describe a method of delivering a therapeutic agent. Support for the method claims is found in paragraph [0052] of the published application.

Section 112 Rejections

Claims 2, 3, and 15 have been rejected under 35 U.S.C. § 112 as failing to comply with the written description requirement. The Examiner believes that claims contain subject matter that was not described in the specification in such a way to convey to one skilled in the art that the inventors had possession of a claimed invention. Claims 2 and 3 have been amended and new claim 20 added to the application for clarification. Claims 15 has been cancelled. Claim 2 has been amended to recite that the composite sheet is capable of releasing the therapeutic agent for a period of 0 to about 14 days. Support for this amendment is found at paragraph [0047] of the published application. Claim 3 has been amended to recite that the coarse foam material has open face pores for holding and releasing the therapeutic agent having a diameter of about 200 to about 300 microns. Support for this amendment is found in paragraph [0038] of the published application. New claim 20 indicates that the composite sheet is capable of releasing the

therapeutic agent for a period of about 30 days. Support for this new claim is found in paragraph [0047] of the published application. No new subject matter has been added to the application.

One skilled in the art would know from reading paragraph [0047] of the published application how much therapeutic agent should be added to the composite sheet of the present invention to provide a period of therapeutic effectiveness from 0 to 14 days or about 30 days. Zero days refers to immediate distribution.

Section 103 Rejections

The present application names joint inventors. There is no change of inventorship due to the amendment to the claims.

Claims 1, 2, 5–7, 9, 15, and 16 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of U.S. Patent Publication No. 2002/0128578 to Johnston ("the '578 reference"), U.S. Pat. No. 5,352,508 to Cheong ("the '508 reference"), and U.S. Pat. No. 6,183,770 to Muchin ("the '770 reference").

The Examiner has added the '578 reference to the teachings of the previously cited references but still does not make a convincing argument of obviousness for the current claims pending in the present application. The Examiner states that the '578 reference teaches a medical article comprising multiple sheets comprising microchannels useful for wound dressing and drug delivery dressing and notes the abstract and paragraphs [0022], [0073], and [0121] support these points. Further, the Examiner states that the article comprises layers having microchannels that are made of polyurethane or polyvinylacetate to facilitate the delivery of medicaments and an absorbent layer made of foam.

In the '578 reference, paragraph [0022] does not relate to microchannels useful for wound dressing and drug delivery dressing. Paragraph [0022] of the '578 reference states,

> The fluid transportation or "wicking" property may be provided by fluid control film incorporating a microreplicated pattern. The pattern may be provided in the backing or adhesive layer of a dressing, or by a separate piece of film. The storage reservoir is preferably a hydrophilic fabric such as a woven, knit, or non-woven, a hydrocolloid, foam, or a gel system that is able to absorb large amounts of fluid exudate. Preferably a high MVTR transparent or translucent backing is used. Certain dressings may also be used to supply medicaments to the wound such as antimicrobials, antibiotics, growth factors, irrigation fluid, anesthetics/analgesics, and the like. Certain other dressings may incorporate the optional medicaments directly into the adhesive, film backing, or microreplicated fluid transport wick.

Paragraph [0073] also does not mention drug delivery, nor does it teach or suggest drug delivery.

Paragraph [0073] of the '578 reference states,

> Certain articles of the present invention comprise fluid control film components that comprise layers of two or more films. These components are particularly suitable for active fluid transport.

In addition, paragraph [0121] does not recite or teach drug delivery. Paragraph [0121] of the '578 reference states,

> FIG. 1a illustrates one embodiment of a wound dressing 30 of the present invention. Dressing 30 comprises film backing 32 with adhesive surface; absorbent ring 34; and fluid control film 36. The channels in the fluid control film 36 transport fluid from a covered wound site to the absorbent ring 34. Alternatively, as shown in FIG. 1b two pieces of absorbent material (44a and 44b) may be utilized in place of absorbent ring 34 of FIG. 1a. As shown in FIG. 1c, fluid control film 56 comprises a plurality of channels radially extending toward a periphery. Alternatively, as shown in FIG. 1f, fluid control film 56f comprises a plurality of channels in a cross-hatched pattern. In either case, absorbent ring 54 is positioned to absorb fluid transported via the fluid control film. Film backing 52 may be provided with an adhesive layer to facilitate attachment of the dressing to the patient. The dressings of the present invention may also incorporate fenestrations, slits, or other patterns to allow conformability to the patient or to facilitate use of a auxiliary medical device such as an IV tube or wound drain.

None of the paragraphs of the references cited by the Examiner, nor any reference itself, teaches drug delivery, nor do they singularly or in combination instruct one skilled in the art how to deliver drugs in the system described. The abstract of the disclosure does mention "drug delivery dressings" but does not teach one skilled in the art what the phrase means.

The Examiner has cited paragraphs [0023], [0047], and [0048] of the '578 reference as providing descriptions of layers having microchannels made of polyurethane or polyvinylacetate

to facilitate delivery of medicaments. None of the paragraphs of the reference mention, much less teach or suggest, delivery of drugs or medicaments as recited by the Examiner.

Paragraph [0023] of the '578 reference states,

> In another embodiment, drug delivery dressings are provided. The delivery dressings incorporate fluid control film component to facilitate delivery of a medicament to the skin.

Paragraph [0047] of the '578 reference states,

> The channels of fluid control films of the present invention can be of any geometry that provides desired liquid transport, and preferably one that is readily replicated.

Paragraph [0048] of the '578 reference states,

> The invention fluid control films can be formed from any thermoplastic materials suitable for casting, or embossing including, for example, polyolefins, polyesters, polyamides, poly(vinyl chloride), polyether esters, polyimides, polyesteramide, polyacrylates, polyvinylacetate, hydrolyzed derivatives of polyvinylacetate, etc. Polyolefins are preferred, particularly polyethylene or polypropylene, blends and/or copolymers thereof, and copolymers of propylene and/or ethylene with minor proportions of other monomers, such as vinyl acetate or acrylates such as methyl and butylacrylate. Polyolefins are preferred because of their excellent physical properties, ease of processing, and typically lower cost than other thermoplastic materials having similar characteristics. Polyolefins readily replicate the surface of a casting or embossing roll. They are tough, durable and hold their shape well, thus making such films easy to handle after the casting or embossing process. Hydrophilic polyurethanes are also preferred for their physical properties and inherently high surface energy. Alternatively, fluid control films can be cast from thermosets (curable resin materials) such as polyurethanes, acrylates, epoxies and silicones, and cured by exposure to heat or UV or E-beam radiation, or moisture. These materials may contain various additives including surface energy modifiers (such as surfactants and hydrophilic polymers), plasticizers, antioxidants, pigments, release agents, antistatic agents and the like. Suitable fluid control films also can be manufactured using pressure sensitive adhesive materials. In some cases the channels may be formed using inorganic materials (e.g., glass, ceramics, or metals). Preferably, the fluid control film substantially retains its geometry and surface characteristics upon exposure to liquids. The fluid control film may also be treated to render the film biocompatible. For example, a heparin coating may be applied.

To reiterate, the above-cited paragraphs do not mention, much less teach or suggest, a method of delivering drugs from a medical article composite sheet described in the claimed invention. The Examiner has stated that the system described in the '578 reference discloses an absorbent layer made of foam in paragraphs [0107] and [0209]. The referenced paragraphs recite

an optional absorbent material that includes fibrous textile-type materials, including woven, nonwoven, knit, and stitch-bonded materials or absorbent foams. The polymer foam material claimed in the present invention includes polyurethane, polyvinylacetate, polyvinyl alcohol, and polyethylene. None of these materials are recited in the noted paragraphs or at all in the '578 reference. Rather, the '578 reference relates to a system for removing liquids from the wound site by a wicking action. The fluid control film of the '578 reference comprises a sheet material having microchannels that permit directional flow of the liquid *away* from wound surface, not *toward* the surface of the skin for administration and treatment. Clearly, one skilled in the art would not be motivated to use the teachings of the '578 reference to reconstruct the claimed invention.

The Examiner states that the '508 reference teaches wound dressing comprising a net substrate encapsulating an hydrophilic tacky resin coating leaving the apertures in the net substrate unoccluded to prevent skin occlusion or damage to the healthy skin. Left uncited by the Examiner is the fact that the substrate is a net, not a substrate filled with microchannels. The net, as one would imagine, has apertures similar to the construction of a fishing net. As stated in the '508 reference, column 1, lines 55–65, the net dressing may be made from natural or synthetic fibers; may be woven, knitted, or nonwoven; and has a regular pattern of apertures, generally having a diameter or width of 0.5 to 5 mm. The dressings are generally used on wounds that are exuding large amounts of fluid, and the dressing acts as a nonabsorbent layer placed between the wound and an absorbent layer to prevent the absorbent layer from sticking to the wound. It would be difficult for one skilled in the art to imagine the claimed invention in view of a disclosure of this nature in the '508 reference. Applicant's claimed invention, with its polymer foam material and polymer enrobing material with microchannels passing through, has no need

for a nonabsorbent layer placed between the wound and an absorbent layer, nor does it have a need for woven, knitted, or net substrate, nor does it have a requirement that the apertures be patterned after a fishnet structure having a diameter of 0.5 to 5 mm. Clearly, these features teach away from the claimed invention. If they were to be combined with the '508 reference, there would still be no teaching or suggestion of the claimed invention. The combination would result in microchannels running parallel to the surface of the skin to wick moisture from the wound with a net-like substrate having apertures with a width of 0.5 to 5 mm. Further, the net dressing would be made of natural or synthetic fibers, which are woven, knitted, or nonwoven. The combination would not motivate one skilled in the art to practice the currently claimed invention.

The Examiner has cited the '770 reference, allegedly to show the delivery of active agents in a pad placed next to the skin. The '770 reference discloses a pad having an upper and lower surface area with an adhesive adhering to the lower surface area of the pad. There may be additional layers between the upper and lower surface areas. In addition, there are defined apertures for medicaments to be delivered to the skin. In the presently claimed invention, an adhesive is neither required nor claimed to hold the composite sheet to the skin. A plurality of microchannels are utilized for administering an agent to the polymer foam and polymer enrobing material for distribution to the skin or wound. No adhesive is required. The '770 reference does not disclose microchannels or delivery of medicaments to the skin surface. It is not readily apparent how the teachings of the '770 reference can be combined with the teachings of the '578 and the '508 references to lead one skilled in the art to the presently claimed invention. The invention would require channels running parallel to the surface of the skin to wick fluid from the wound surface, away from the wound, having a net substrate similar in structure to a fishing net, having apertures ranging from 0.5 to 5 mm, with a plurality of layers, with the lower layer

contacting the skin and being made from an adhesive. Even with an attempt to reconstruct the claimed invention by hindsight analysis, knowing the Applicant's claimed invention and then searching for bits and pieces in the prior art to reconstruct the claimed invention, the combination fails. The references, taken either singularly or in combination, do not teach or suggest the presently claimed invention.

Claims 3, 4, 8, and 19 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combination of the '578, the '508, and the '770 references in further view of U.S. Patent No. 6,326,410 to Cheong ("the '410 reference"). The Examiner is adding the '410 reference to attribute the combination of references to disclose pore size.

The Examiner believes the '410 reference teaches polyurethane foam having pore sizes between 0.01 and 0.6 mm that allegedly are within the claimed range of pore sizes in the present invention of 200 to 300 microns. The pore sizes disclosed in the '410 reference do not appear to be material. The '410 reference discloses a method of forming a polyurethane foam suitable for use as a wound contacting layer. If this is the purpose of the disclosure, the disclosure does not teach or suggest the use of microchannels, and the use of an enrobing polymer material, which encapsulates the polymer foam material, which subsequently holds and releases or disperses the therapeutic agent onto the skin. Clearly, there is no teaching of the polymer enrobing material claimed by Applicant in this reference or any of the other references cited by the Examiner. The enrobing polymer of the claimed invention enrobes or encircles the composite sheet, including the side or sides of the composite sheet, whether shape of the sheet is circular or three- or four-sided is immaterial. The enrobing material allows for distribution of the therapeutic agent to the skin. Indeed, the combination of references, even when taken in view of hindsight analysis of the

currently claimed invention, would not lead one skills in the art to the presently claimed invention.

Conclusion

The claims define a composite sheet and method of delivering a therapeutic agent to the skin containing a flexible, porous, polymer foam material for holding and releasing the agent, a polymer enrobing material encapsulating the polymer foam material, which contacts the skin and a plurality of microchannels passing through the enrobing material and polymer foam material for holding and releasing the agent. The agent is released or dispensed from the microchannels into the polymer foam material and polymer enrobing material for distribution to the skin. The microchannels can also release the agent to the skin surface while it releases the agent through the foam material and polymer enrobing material.

It is respectfully submitted that the claims define patentable subject matter over the references cited. An early Notice of Allowance of the claims as presented is respectfully requested. The Commissioner is hereby authorized to charge any underpayment or credit any overpayment to Deposit Account No. 22-0259 or any payment in connection with this communication, including any fees for new claims that may be required. The Examiner is invited to contact the below listed attorney if the Examiner believes that a telephone conference will advance the prosecution of this application.

Respectfully submitted,

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